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PHARMACY NEWSLETTER

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Pharmacy Newsletter provides information regarding the decisions of P & TC, current concepts in drug therapy, warnings and cautions issued by various regulatory agencies, drug interactions, ADRs and matters related to drug usage.

Opinions expressed are of authors and does not necessarily represent AKUH's view/recommendations.
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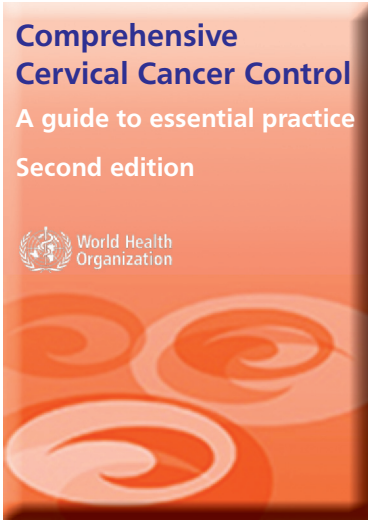
Inside this Issue:

New WHO Guide to Prevent and Control Cervical Cancer

Ale zehra, Clinical Pharmacist



Cervical cancer is one of the world's deadliest but most easily preventable forms of cancer for women, responsible for more than 270000 deaths annually, 85% of which occur in developing countries. An estimated one million-plus women worldwide are currently living with cervical cancer. On 3rd December 2014, the new "Comprehensive cervical cancer control"(also known as pink book) was launched by WHO. The new WHO guide provides a comprehensive cervical cancer control and prevention approach for governments and healthcare providers.
The main elements of the new guide are:

- **Vaccinate 9 to 13-year-old girls** with two doses of Human papillomavirus (HPV) vaccine to prevent infection with the HPV. The reduced, 2-dose schedule has been shown to be as effective as the current 3-dose schedule.
- Use HPV tests to screen women for cervical cancer prevention. With HPV testing, the frequency of screening will decrease. Once a woman has been screened negative, she should not be rescreened for at least 5 years, but should be rescreened within 10.

The new guide line identifies key opportunities and ages throughout a woman's life when cervical control and prevention can be put into action, especially for:

- **Primary prevention:** human papillomavirus (HPV) vaccination targets girls aged 9 to 13 years, aiming to reach them before they become sexually active.
- Secondary prevention: access to technology for women over 30 years of age, such as VIA (visual inspection of the cervix with acetic acid) or HPV testing for screening, followed by treatment of detected precancerous lesions, which may develop into cervical cancer.
- Tertiary prevention: access to cancer treatment and management for women of any age, including surgery, chemotherapy and radiotherapy.
- When curative treatment is no longer an option, access to palliative care is crucial.

Analgesic use in Adult Patients with Advanced Chronic Liver Disease or Cirrhosis

Dr. Hafsah M. Ashfaq, Pharmacist.

Patients with liver disease may develop acute or chronic pain from a variety of causes. In addition to causes common in the otherwise healthy population, those with advanced liver disease may have ascites (leading to abdominal and lower back pain) and gynecomastia (leading to mastalgia).
Management of pain in patients with liver disease raises special concerns. The choice of appropriate analgesic agents requires a thorough understanding of their pharmacokinetic and side effect profiles.

	Altered Response and Pharmacokinetics	Management Suggestions
Non-opioid analgesics		
Acetaminophen (Paracetamol)	Glutathione tissues are reduced in individuals with cirrhosis, thereby lowering the dose threshold of acetaminophen that can be safely administered each day.	• Acetaminophen is generally well tolerated in patients with CLD or cirrhosis, provided the total daily dose is limited to no more than 2 g/day (4 tablets of 500mg/day) • Also note that Paracetamol is available in combination of other pain killers and muscle relaxants also so same caution should be exercised in these products. E.g. Nuberol, Nuberol Forte, Codogesic etc.
Non-selective NSAIDs	NSAIDs can decrease GFR and impair renal function in patients with advanced CLD or cirrhosis.	NSAIDs and aspirin should be avoided in patients with advanced CLD or cirrhosis.
Selective COX-2 inhibitors	Excess cardiovascular events have been observed with this class of medications when used by patients without cirrhosis.	If used, Celecoxib product information suggests a 50% dose reduction for Child-Pugh class B cirrhosis.
Opioid analgesics (see NOTE)*		
Fentanyl	Parent drug can accumulate after repeated dosing or when administered as a continuous infusion due to tissue and protein binding.	Generally a good choice for patients with CLD or cirrhosis when opiate treatment indicated. With repeated dosing, reduce dose and frequency by approx. 25-50%
Morphine	Half-life can be increased by twofold. Accumulation of metabolites with complex effects can occur in patients with cirrhosis and renal failure.	Reduce dose and frequency by approx. 50 % Avoid in patients with cirrhosis and renal failure as much as possible
Tramadol	Unpredictable onset, variable analgesic efficacy, and risk of accumulation in patients with cirrhosis.	Avoid use in patients with decompensated cirrhosis. A reduced dose of 25 mg every eight hours may be considered.

	Altered Response and Pharmacokinetics	Management Suggestions
Meperidine (Pethidine), Codeine	Unpredictable analgesic efficacy and increased risk of toxicity in CLD or cirrhosis patients.	Meperidine/Pethidine and Codeine should be avoided in such patients
Adjunctive agents for neuropathic pain		
Gabapentin	Not hepatically metabolized, dependent upon renal clearance. Sedation and dizziness may limit usefulness in patients with advanced CLD or cirrhosis.	Initiate treatment at 300 mg orally per day and gradually titrate dose. Maintenance dose is dependent upon renal function.
Pregabalin	Not hepatically metabolized, dependent upon renal clearance. Sedation and dizziness may limit usefulness in patients with advanced CLD or cirrhosis.	Initiate treatment at 50 mg orally twice per day and gradually titrate dose. Maintenance dose is dependent upon renal function.
Nortriptyline	Accumulation of metabolites in hepatic impairment is less likely with Nortriptyline.	Initiate treatment at 10 mg orally HS and gradually titrate dose
Carbamazepine	Carbamazepine has been associated with hepatotoxicity and serious allergic reactions	Carbamazepine should be avoided

* NOTE: All opioids can worsen or precipitate Hepatic Encephalopathy and should be used cautiously or avoided in patients with portal hypertension and preexisting Hepatic Encephalopathy

The Novel Treatment of Clostridium Difficile Associated Diarrhea (CDAD)

Harris Ahmed, Trainee Pharmacist

The emergence of *Clostridium difficile* associated disease (CDAD) is one of the important problems associated with widespread antibiotic use. Alteration of natural gut flora due to broad-spectrum antibiotic use leads to gut colonization by the aerobic, gram-positive, spore producing bacillus *Clostridium difficile. C. difficile* produces potent exotoxins that cause inflammatory, secretory diarrhea and colitis; in severe cases it may even lead to death. Any antibiotic may predispose to colonization by *C. difficile,* including Metronidazole and Vancomycin, the two first line agents used to treat CDAD. Thus hospitals must have a solid antimicrobial stewardship program that ensures rational antibiotic use to minimize the growth, emergence and increasing virulence of *C. difficile.*

Treatment of *Clostridium Difficile*	
Antibiotic Therapy	
Initial Episode:	**Oral Metronidazole:** 500 mg Q8H or 250 mg Q6H for 10 to 14 days
	Oral Vancomycin: 125 mg orally Q6H for 10 to 14 days **Rectal Vancomycin:** 500mg in 100ml NS Q6h + **Metronidazole IV**
First relapse	Repeat treatment as in initial episode above. Alternative: Fidaxomicin[1] 200 mg orally q12h for 10 days
Second relapse	**Tapering and pulsed oral Vancomycin :** 125 mg PO Q6H for 7 to 14 days ➡ 125 mg PO Q12H for 7 days 125 mg PO QD for 7 days ➡ 125 mg PO every other day for 7 days ➡ 125 mg PO QD every 3 days for 14 days. **Alternative:** Fidaxomicin1 200 mg PO Q12H for 10 days
Subsequent relapse	**Fidaxomicin[1]** 200 mg orally twice daily for 10 days if not used previously **Fecal bacteriotherapy** (fecal microbiota transplant) Consider anion binding resins with Vancomycin
Studies of Rifaximin:	Some studies have shown that sequential therapy with Vancomycin followed by Rifaximin may be effective for recurrent *Clostridium difficile*. However, exposure to rifamycins prior to development of CDI is a risk factor for rifampin-resistant *C. difficile* infection.
Non- Antibiotic Therapy	
Fecal Microbiota Transplant (FMT):	Single to multiple infusions of bacterial fecal flora originating from a healthy donor via a colonoscopy, an enema or a nasogastric tube
Anion Binding Resins	It's used as an adjuvant 2-3 hours apart from Vancomycin. It neutralizes the exotoxins produced by C. difficile. Example: Colestyramine, Colestipol[1], Tolevamer[1]
Intravenous Immunoglobulin (IVIG)	It contains a C. difficile antitoxin and has been used in some patients with recurring CDI. Its effectiveness has not been properly elucidated
Probiotics	Effective in mild CDI

[1]*Not yet registered in Pakistan*

Proton-Pump Inhibitors (PPIs) – Are we over using them?

Dr. Salwa Ahsan - Manager Inpatient Pharmacy

Proton-pump inhibitors (PPIs) remain the major evidence-based therapy for upper GI disorders, including GERD, dyspepsia, and peptic ulcer disease. The strong evidence supporting PPI efficacy and a favorable safety profile may have contributed to significant over-prescription, exposing patients to an increasing number of potential risks.

- In ambulatory care setting, the overutilization of PPIs is often a result of failure to re-assess the need for continuation of therapy, or insufficient use of on-demand and step-down therapy.
- PPI overutilization in the inpatient setting is often a result of inappropriate stress ulcer prophylaxis (SUP) in non-intensive care unit patients, and failure to discontinue SUP prior to hospital discharge.

Indication in Inpatient:

From an inpatient perspective, appropriate initiation of PPI treatment would be limited to primary conditions requiring directed therapy such as undifferentiated upper GI bleed, duodenal or gastric ulcer, or erosive esophagitis] or a select population of intensive care unit (ICU) patients requiring prophylaxis.

Stress Ulcer Prophylaxis (SUP):

Prophylaxis is generally recommended in patients who are critically ill with risk factors for physiological stress-related bleeding, including respiratory failure, coagulopathy, sepsis, severe hypotension, acute renal failure, history of GI ulcer or a GI bleed within 1 year of admission, hepatic failure, major trauma, burns, spinal cord injury, organ transplantation, Glasgow Coma Score up to 10, surgery, high-dose corticosteroid therapy, renal failure, or ICU stay of at least 6 days.
Patients receiving SUP should be assessed daily and when their risk factors resolve and clinical condition improves, discontinuation of SUP should be considered. Enteral nutrition may have prophylactic benefit in patients who are critically ill by optimizing splanchnic blood flow, enhancing secretion of cytoprotective prostaglandins, buffering acid, or other mechanisms – thus can be considered.

Discontinuation of SUP should also be considered when patients are transferred out from the ICU. Outside of the ICU, the only indications for initiation of PPI in the inpatient setting are GI diagnoses or conditions that warrant treatment.

Potential consequences of prolonged PPI therapy:

This includes hypergastrinemia, enterochromaffin-like cell hyperplasia, and parietal cell hypertrophy, leading to rebound acid hypersecretion.
PPIs have been linked via retrospective studies to increased risk of enteric infections including *Clostridium difficile*-associated diarrhea, community-acquired pneumonia, bone fracture, nutritional deficiencies (Vitamin B12 (cobalamin) deficiency), and possible interference with metabolism of antiplatelet agents.
Reducing inappropriate prescribing of PPIs in the inpatient and outpatient settings can minimize potential for adverse events, and foster controllable cost expenditure.

Duration of therapy:

The Food and Drug Administration (FDA) advises that no more than three 14-day treatment courses should be used in one year in order to avoid side effects induced by PPI.

Available PPIs in AKUH Formulary with Price (per unit):

Drugs	IV	PO[1]	Indication in Pediatrics*	Dosing	Comments
Omeprazole**	40 mg 289/-	20 mg, 13.57/- 40 mg, 18.5/-	1 year and older	Once daily	Daily dosages of > 80 mg should be administered in divided doses
Esomeprazole	-	20 mg, 11.5/- 40 mg, 20/-	1 year and older	Once daily	Twice daily for pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome
Pantoprazole	-	40 mg, 62/-	5 years and older	Once daily	

** As per manufacturer*
***compounded oral solution is also available*

[1]administer 30 minutes before meal on empty stomach. Granules of capsule must not be crushed- use oral solution if to be given through NG tube.

Characteristic	Omeprazole	Pantoprazole	Esomeprazole
Bioavailability (%)	30 to 40	77	90% (repeated once-daily dosing) and 64% (single dose)
Time to peak plasma concentration (hours)	0.5 to 3.5	1.1 to 3.1	1.5
Plasma elimination half-life (hours)	0.5 to 1.0	1.0 to 1.9	1 to 1.5
Protein binding (%)	95	98	97
Urinary excretion of oral dose (%)	77	71 to 80	1
Duration of action (hours)	24	24	24

IV to PO Switch Guidelines

Drug & Poison Information Team

Introduction

IV to oral switch is the prompt conversion of IV antibiotic therapy to oral. Patients may be considered candidates for switching from IV to oral therapy once the patient has shown clinical improvement and is medically stable.

Rationale

The majority of patients with a severe infection who are adequately absorbing oral medication and initially require IV therapy can be safely switched to oral therapy within 48 hours. There are a number of advantages to support the prompt switch from IV to oral therapy these are as follows 1,2,3:

- Reduction in the likelihood of hospital acquired bacteraemia and infected/phlebitic IV lines.
- Saves both medical and nursing time
- Reduces discomfort for patients and enables improved mobility and the possibility of earlier hospital discharge.
- Potential to significantly reduce treatment costs.
- Patient is more likely to receive antibiotics at the correct time.
- Potential reduction in the risk of adverse effects; errors in preparation are significantly higher with parenteral drugs, compared to oral formulation.

Considerations for the early switch to oral therapy: COMS (review at 24-48 hours)
C Clinical improvement observed
O Oral route is not compromised (vomiting, malabsorptive disorder, swallowing problems, unconscious, severe diarrhea)
NB: if NG/PEG feeding then please consult your pharmacist for appropriate dosage form
M Markers showing a trend towards normal: Patient should be afebrile for the last 24 hours (Temp >360 C and <380 C) and DO NOT have more than one of the following, heart rate >90/min, resp rate >20/min, BP unstable, WBC<4 or >12 (WBC/neutrophils should show a trend towards normal); absence of such should not impede the switch if all other criteria are met and not neutropenic.

S Specific indication/deep-seated infection (Prior to switch refer to table 1)

High risk/deep-seated infections

Certain infections may appear to respond promptly to intravenous therapy, but warrant prolonged IV therapy. This is to ensure that adequate drug levels are attained at the site of infection and to optimize the response and prevent relapse.

Discuss with Microbiology before switching patients with a high risk/deep seated infection to oral therapy.

Deep seated infections that may require an initial 2 weeks of IV therapy	High risk infections requiring prolonged IV therapy
• Liver abscess	• Staphylococcus aureus bacteraemia
• Osteomyelitis, Septic arthritis	• Severe necrotizing soft tissue infections
(N.B. high-dose oral Clindamycin may be appropriate once patient is stable)	• Severe infections during chemotherapy related neutropenia
• Empyema	• Infected implants/prosthesis
• Cavitating pneumonia	• Meningitis/encephalitis
	• Intracranial abscesses
	• Mediastinitis
	• Endocarditis
	• Exacerbation of cystic fibrosis/bronchiectasis
	• Inadequately drained abscesses or empyema

Proud to Report

Best Oral Presentation at 7th Medication Safety Conference, Abu Dhabi, UAE.

The 7th Medication Safety Conference 2014, Abu Dhabi, UAE: the best oral presentation award won by Ms. Farhat Zaheer (specialist, Compounding, IV admixture & Chemo section) and her team .Title of the project was "Strategies to enhance and reduce turnaround time of sterile and non-sterile compounding preparations for ambulatory care patients" Approximately 140 entries from 50 different countries were presented, while AKUH's entry presented by Ms. Farhat Zaheer was declared the winner. This was a quality improvement project related to process re-designing and innovative strategies that bring efficiency and reduce turn around timings of sterile/non-sterile compounded medications for ambulatory care patients at AKUH.

25th September, World Pharmacist Day-Celebration

Department of Pharmacy Services at the AKUH celebrated World Pharmacist Day(cake cutting + symposium+ stall) in collaboration with the Society of Hospital Pharmacists of Pakistan and Hospital Pharmacy Section of FIP-International Pharmaceutical Federation based in Hague, The Netherlands. Such platform identifies the contributions of pharmacist along with other health care professionals in developing a better health and ultimately bringing better quality to life.